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EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/11/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/777,091

Applicant(s)

PAVCHNIK ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-36 and 42-55 is/are pending in the application.
- 4a) Of the above claim(s) 7-9,14,17,18,23,24,31-35 and 42-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,10-12,15,16,19-22,25-30,36 and 46-55 is/are rejected.
- 7) ☒ Claim(s) 6 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. Applicants' cancellation of claims 3 and 37-41 in Paper No. 25 is acknowledged.

Claim Objections

2. Claims 4, 5, 36, 46, 50, and 55 are objected to because of the following informalities:
 - a. Regarding claims 4 and 5, both depend on recently cancelled claim 3.
 - b. Regarding claim 36, for reasons of clarity, please substitute "the arcuate edge" (see lines 6-7) with --said first arcuate outer edge--.
 - c. Regarding claim 46, "therearound" (see line 21) was not found in the dictionary. Examiner respectfully suggests substituting "therearound" with --around the walls--. Also, please add --along-- after "longitudinally" (see line 20).
 - d. Regarding claim 50, for reasons of clarity, (i) please add --each-- after "leaflets" (see line 3), (ii) please add --the outer edge of-- after "extending along" (see line 8).
 - e. Regarding claim 55, please substitute "a" (line 8, second occurrence) with --an--.Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the lack of a support structure (i.e., frame) to hold/support the claimed plurality of leaflets or the claimed covering.

Note: As mentioned in the last office action (Paper #22), elected species K shows a covering/plurality of leaflets attached to a frame (see Figures 21, 22, 23, 24, 25, 26, 26A, 27, and 50). Applicants referred to page 18, lines 8-22 to show a "frame being formed from the same material as the leaflet". Page 17, line 28 to page 19, line 22, refers to Figures 20-27 and 35-41, all of them showing a plurality of leaflets (or a covering) attached to a frame. The Examiner could not find any language describing the frame as "being formed from the same material as the leaflet" or describing the frame as including "both separate and integral structure".

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 11, 19-22, 25-30, and 46-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

From the marked-up copy of the claims submitted/filed June 11, 2003 (Paper # 27):

a. Claim 2 recites the limitation "The vascular valve" in line 1. There is insufficient antecedent basis for this limitation in the claim. This was addressed in the last office action (Paper #22).

b. Claim 2 recites the limitation "the free edge" in line 2. There is insufficient antecedent basis for this limitation in the claim. This was addressed in the last office action (Paper #22).

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c. Claim 11 recites the limitation "the extracellular collagen matrix" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. This was addressed in the last office action (Paper #22).

d. Claim 19 recites the limitation "the second end" in line 5. There is insufficient antecedent basis for this limitation in the claim. This was addressed in the last office action (Paper #22).

Claims 20-22, 25-30, 48, and 49 depend on claim 19.

e. Regarding claim 46, because of the newly added language, the limitation "adapted to engage the walls of the bodily passage oriented at least partially longitudinally the walls" (see lines 19-20) renders the claim vague and indefinite. From that claim language, it is not clear if the structure oriented "at least partially longitudinally the walls" is referring to "the bodily passage" or to each "leg of the pair of legs".

f. Claim 47 recites the limitation "the second end" in line 6. There is insufficient antecedent basis for this limitation in the claim. This was addressed in the last office action (Paper #22).

g. Regarding claim 50, "the supporting frames" (see line 8) lacks antecedent basis. Also, "they" (see line 9) lacks antecedent basis since it is not clear to what "they" is referring to. Furthermore, the limitation "are interconnected by a series of bends such that they collectively assume a generally serpentine configuration" (see lines 8-10) renders the claim vague and indefinite as to the scope of the invention since, according to the specification, the legs of the frame are the ones that are interconnected by bends.

h. Regarding claim 51, the language disclosed in lines 3-9 renders the claim vague and indefinite. It seems from that language that the plurality of legs and the support frame are two

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separate structures. There is no structural link between the plurality of legs and the support frame. Claims 52-54 depend on claim 51.

i. Regarding claim 52, the limitation "the plurality of legs each include a first and second bend oriented in a first direction and at least one bend in an opposite direction" (see lines 1-3) is confusing and renders the claim vague and indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 19, 28, 36, and 48 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boretos et al. (US 4,222,126). As seen in Figures 1-4, Boretos et al. disclose an implantable valve comprising a frame (frame 12) including a plurality of legs (struts 12a, 12b, 12c, area between struts 12a, 12b, 12c, and reinforcement lines 22) generally assuming a serpentine configuration (see Figure 1), and a plurality of leaflets (leaflets 14a, 14b, and 14c) which outer edge is at least partially attached to, and reinforced by one of the plurality of legs (see Figures 1 and 4; see column 6, line 66 to column 7, line 7). The covering or plurality of leaflets defines arched or arcuate surfaces ending in an orifice (see Figure 2) to permit fluid flow in a first direction while occluding fluid flow in a second direction (see Figure 1).

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9. Claims 19, 28, 36, and 48 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Reul (US 4,291,420). As seen in Figure 1, Reul discloses an implantable valve comprising a frame (suture ring 1) including a plurality of legs (U-shaped legs; see column 4, lines 10-15) generally assuming a serpentine configuration (see Figure 1), and a plurality of leaflets (pockets 2) of flexible material defining an opening when blood flows in one direction and trapping fluid between the leaflets and the inner wall of a bodily passage when blood flows in the opposite direction (see claim 1; see entire document).

10. Claim 36 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cox (US 5,713,950 A; cited in Applicant's IDS). Cox discloses replacement heart valves comprising a covering or plurality of leaflets made from a collagen material (i.e., small intestinal submucosa or SIS; see Figures 1-8; see Abstract; see column 25, lines 4-10). The covering or plurality of leaflets define arched or arcuate surfaces ending in an orifice (see Figures 2-6) to permit fluid flow in a first direction while occluding fluid flow in a second direction (see Figures 2-6; see column 21, lines 25-36; column 23, lines 30-39). The covering or plurality of leaflets is sutured to either a valve annulus or to an annuloplasty ring (see column 21, lines 23-24; column 23, lines 28-29). From the marked-up copy of the claims submitted/filed June 11, 2003 (Paper # 27), claim 36 does not claim a support frame.

11. Claims 36, 50-54, are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bessler et al. (US 5,855,601 A; cited in Applicant's IDS). Bessler et al. disclose a heart valve comprising a frame (i.e., self-expanding stent 21 or 32) and a valve member/covering 22 (or 35) shaped as a plurality of arcuate and flexible leaflets 24 (see Figures 1, 2, and 4; see column 3, lines 65-67; column 4, lines 1-3; column 5, lines 21-27 and lines 34-38; column 6, lines 3-7).

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The valve member/covering 22 (or 35) is made of a biocompatible material (see column 6, lines 19-31). The plurality of leaflets defines an orifice which open in response to blood flow in one direction and close in response to blood flow in the opposite direction (see column 3, lines 65-67; column 4, line 1). The stent is formed in a zig-zag or serpentine configuration (see Figures 1, 4, and 6; see column 5, lines 54-55) and may comprise a plurality of barbs (see Figure 6) for fixing the valve in a desired position (see column 4, lines 12-14). The straight portions of the stent are joined by bends 54 (see column 5, lines 55-58).

12. Claims 1, 2, 4, 5, 12, 36, and 50-54 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Moll et al. (US 6,287,334 B1; cited in Applicants' IDS). As seen in Figures 1-6, Moll et al. disclose an implantable valve comprising a support frame (support frame 10) providing a plurality of side elements defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall (see Figures 1 and 2), and a plurality of leaflets (valve elements or blood flow stoppage elements 6) which inner edges define an opening to permit fluid flow in a first direction (see Figure 5) and engage each other to restrict fluid flow in a second opposite direction (see Figure 6). The outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements (see Figure 1; see entire document).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 20-22 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos et al. (US 4,222,126) in view of Bessler et al. (US 5,855,601 A; cited in Applicant's IDS). Boretos et al. disclose an implantable valve essentially as claimed (see 102(b) rejection above). Although Boretos et al. describe the material of frame 12 as polyurethane or "a combination of these and others that have biocompatibility and strength" (see column 6, lines 8-12), they do not specifically disclose a metallic frame. However, Bessler et al. disclose an implantable valve comprising a frame or stent member made from "Elgiloy alloy, titanium, titanium alloy, nitinol, stainless steel, or other resilient, flexible non-toxic, non-thrombogenic, physiologically acceptable and biocompatible materials" (see column 6, lines 3-8). Bessler et al. is evidence of frame or stent members made from several materials as long as they provide non-thrombogenic, physiologically acceptable and biocompatible characteristics to the frame. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a metallic frame, as taught by Bessler et al., with the valve of Boretos et al., in order to provide non-thrombogenic, physiologically acceptable and biocompatible characteristics to the frame.

15. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos et al. (US 4,222,126) in view of Cox (US 5,713,950 A; cited in Applicant's IDS). Boretos et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. However, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see

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column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Boretos et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

16. Claims 47 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. (US 5,855,601 A; cited in Applicant's IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS). Bessler et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. However, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Bessler et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

17. Claims 10, 11, 46, 47, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 6,287,334 B1; cited in Applicants' IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS). Moll et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. However, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the

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risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Moll et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

18. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 6,287,334 B1; cited in Applicants' IDS) in view of Bessler et al. (US 5,855,601 A; cited in Applicant's IDS). Moll et al. disclose the invention as claimed except for disclosing the use of barbs to anchor the implantable valve to the wall of the bodily passage. However, the use of barbs/hooks to anchor stents to bodily passages is well known in the art. For example, Bessler et al. teach the use of a plurality of barbs 64 for holding a valve in place once it has been appropriately positioned (see Figures 6 and 7; see column 5, lines 12-14; column 5, line 67 to column 6, line 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a plurality of barbs, as taught by Bessler et al., with the valve of Moll et al., in order to hold the valve in place once it has been appropriately positioned.

Response to Arguments

19. Regarding 102(e) rejection over Bessler et al. '601, Applicant's arguments filed February 19, 2003 have been fully considered but they are not persuasive.

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a. Regarding claim 36, Applicants argue that Bessler et al. '601 does not teach "trapping fluid between the leaflet and the vessel wall to close the valve". Examiner respectfully disagrees. Bessler et al. '601 teach that valve means includes a "generally arcuate center portion" and a "peripheral upstanding cuff portion" (see column 3, lines 55-57). The "generally arcuate center portion" is transverse to the stent walls and also "at some acute angle relative to the stent walls" (see column 3, lines 57-60). This is shown in Figure 4. Bessler et al. '601 also teach that the arcuate portion "contains at least one slit to form leaflets which open in response to blood flow in one direction and close in response to blood flow in the opposite direction" (see column 3, line 65 to column 4, line 3). Because of that arcuate portion, there will be blood trapped between the leaflet(s) and the vessel wall when valve close in response to blood flow in the opposite direction.

20. Applicant's arguments with respect to claims 1, 19, 36, 46, and 47 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

21. Claims 29 and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

22. Claims 6 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

24. This application contains claims 7-9, 14, 17, 18, 23, 24, 31-35, and 42-45 are drawn to an invention nonelected with traverse in Paper No. 21. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:30 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

A stylized, handwritten signature consisting of a large, looped 'J' followed by a 'G' and a 'B'.

August 28, 2003

A handwritten signature in cursive script, appearing to read 'David H. Willse'.

David H. Willse
Primary Examiner